

Appl. No. : 10/766068
Filed : January 28, 2004

AMENDMENTS TO THE DRAWINGS

Applicant respectfully requests the following corrections:

In the legend of Fig. 3, "BIAS (V)" is corrected to --BIAS (mV)--.

In the legend of Fig. 4, "700mV CONSTANT" and "800Mv, 1h" are corrected to --700mV, 2h-- and --800mV, 2h--, respectively.

Figs. 8 and 9 have been amended to indicate --Background Art-- because only that what is old is illustrated.

REMARKS

The claims have been amended to clarify the invention and correct informalities.

In the drawings, Figs. 3 and 4 have been amended to correct clerical errors in the legend. Support for the above corrections can be found in the description of Example 1, at page 33, the last paragraph, for example. Further, Figs. 8 and 9 have been amended to indicate --Background Art-- because only that what is old is illustrated.

The disclosure has been amended to correct a translational error.

No new matter has been added. Applicant respectfully requests entry of the amendments and reconsideration of the application in view of the amendments and the following remarks.

Drawings

The Office action states that Figs. 8 and 9 should be designated by a legend such as --Prior Art--. Figs. 8 and 9 have been amended in light of the remarks, thereby obviating this objection.

Claim Objections

Claims 12 and 13 have been objected to as being of improper dependent form. Claims 12 and 13 have been rewritten in independent form and amended to clarify the subject matter recited therein. This objection is now moot.

Drawing Objection

Drawings has been objected to for the inclusion of Figs. 6 and 7. These figures have been canceled, thereby obviating this objection. In accordance with the cancellation of Figs. 6 and 7, the corresponding figure description has been deleted.

Claim Rejection – 35 U.S.C. § 112

Claims 12 and 13 have been rejected under 35 U.S.C. § 112, first paragraph, with regard to the means-plus-function limitations. Applicant respectfully traverses this rejection.

Fig. 2 illustrates a schematic appearance diagram of the measuring apparatus, which is composed of a sensor cartridge portion 7 and a main body 9 in which a signal detection circuit including at least “means for applying a bias between the working electrode and the reference

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electrode”, “means for detecting a signal measured by the chemical sensor”, and a “notification device”. As explained in the section titled “Disclosure of Invention”, the claimed chemical sensor type measuring apparatus is typically a chemical sensor type measuring apparatus of amperometric chemical sensor type, in which an enzyme electrode is used.

As to the “means for applying a bias between the working electrode and the reference electrode” and the “means for detecting a signal measured by the chemical sensor” to be employed in the amperometric chemical sensor using the enzyme electrode, Example 1 provides an example of the “means for applying a bias between the working electrode and the reference electrode” and the “means for detecting a signal measured by the chemical sensor” as “a potentiostatic circuit for supplying a predetermined constant bias to be working electrode 2 and a measuring circuit therewith.” The signal detection circuit used in an amperometric chemical sensor that employs “a potentiostatic circuit for supplying a predetermined constant bias to chemical sensor being set to a three-electrode type constituted of the working electrode and counter electrode of Pt, and the reference electrode of Ag/AgCl and a measuring circuit therewith” is commonly known in the technical field of amperometric chemical sensors.

In view of the foregoing, the disclosure in Example 1, for example, is sufficient for one of ordinary skill in the art to understand typical structures corresponding to the “means for applying a bias between the working electrode and the reference electrode” and the “means for detecting a signal measured by the chemical sensor” to be employed in the amperometric chemical sensor using the enzyme electrode. Thus, claims 12 and 13 as amended herein comply with the requirements of 35 U.S.C. § 112, first paragraph, and Applicant respectfully requests withdrawal of this rejection.

Claims 1-20 have been rejected under 35 U.S.C. § 112, second paragraph, with regard to the limitation “further comprising”. The claims have been amended by deleting the limitation “further comprising” and clarifying the subject matter. This rejection is now moot.

Rejection Under 35 U.S.C. § 103

Claims 1-3, 5, 10-13, and 15 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Inamoto (US5353349) in view of Cozzette (US5112455). Claims 1, 11, 12, and 13

are independent and have been amended to clarify the subject matter recited therein. Claim 1 recites, among others:

the method comprising the following procedure for initial treatment, at the stage of making first use of the chemical sensor:

as a first bias application after immersing the chemical sensor kept under a dry state into the buffer solution to bring the surfaces of the working electrode and reference electrode into contact with the buffer solution,

a first initial treatment step of applying a first initial treatment bias having the same direction as that of the measurement bias and possessing an absolute value larger than that of the measurement bias between the working electrode and the reference electrode to hold the chemical sensor in the buffer solution for a predetermined first initial treatment time;

a second initial treatment step of changing the bias to be applied between the working electrode and the reference electrode to a second initial treatment bias which is the same as the measurement bias, after ending the first initial treatment step, while the chemical sensor is immersed in the buffer solution, and holding the chemical sensor in a standby state; and

after the completion of the second initial treatment step, the chemical sensor is placed for the first time at the use for measurement of the measurement sample,

wherein any bias applied between the working electrode and the reference electrode during said procedure for initial treatment has the same direction as that of the measurement bias.

Due to the procedure for initial treatment (a combination of first high bias followed by measurement bias) recited in the claim, the sensor sensitivity can effectively and quickly be stabilized (e.g., Figs. 4 and 6).

Inamoto teaches that in the reviving method, the interfering on the working electrode which interferes with the turning on of electricity is reduced and the activity of the working electrode is revived **by applying the reverse bias V1** to the working electrode before applying forward bias. See col. 2, lines 55-65. In contrast, in claim 1, the first bias application is an application of forward bias, and no reverse bias is applied. Upon the reading of Inamoto, one of ordinary skill in the art would be directed away from applying solely forward bias as a first bias application. Inamoto teaches away from the claimed initial treatment. (In *Optivus Technology, Inc. v. Loma Linda University Medical Center* (469 F.3d 978 (2006 U.S. App.)), the Court noted that “[a] reference may be said to **teach away** when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant.”).

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Cozzette teaches that to activate the structure, a **set of pulse group** is applied to glucose sensor in the presence of the calibrant or sample fluids, and the process for rapid activation of the electrode surface (**cycling**) the applied potential between values of **opposite sign**. See col. 23, lines 38-44. Further Cozzette states: "The inventors have observed that **negative pulses** are an important aspect of the activation process." See col. 24, lines 29-31 (emphasis added). In contrast, in claim 1, the first bias application is an application of forward bias, and no reverse bias or negative pulse is applied. Upon the reading of Cozzette, one of ordinary skill in the art would be directed away from applying solely forward bias as a first bias application. Cozzette teaches away from the claimed initial treatment.

There is no other evidence provided.

At least in view of the foregoing, a combination of Inamoto and Cozzette cannot lead to claim 1, and also does not provide reasonable expectation of success. Figs. 4 and 6 of the instant application, for example, showing unexpected results are evidence of nonobviousness of claim 1. Thus, the *prima facie* case of obviousness cannot be established.

Claims 11, 12, and 13 as amended herein recite limitations similar to those discussed above for claim 1. At least for the reason, claims 11, 12, and 13 also cannot be *prima facie* obvious over Inamoto and Cozzette (see also Fig. 7 of the instant application for claims 11 and 13). The remaining claims depend from either one of claims 1, 11, 12, and 13, and at least for this reason, the remaining claims also cannot be *prima facie* obvious over Inamoto and Cozzette. Applicant respectfully requests withdrawal of this rejection.

Claims 4, 6-9, 14-15, and 17-20 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Inamoto in view of Cozzette and in further view of Matsumoto (US5795774). These claims depend from either one of claims 1, 11, 12, and 13. Matsumoto teaches a biosensor chip using immobilized enzyme electrode, which is irrelevant to the features discussed for claim 1 above. Thus, a combination of Inamoto, Cozzette, and Matsumoto still cannot lead to claims 1, 11, 12, and 13, and cannot render the claims including claims 4, 6-9, 14-15, and 17-20 obvious. At least for the above reasons, claims 4, 6-9, 14-15, and 17-20 cannot be obvious over Inamoto, Cozzette, and Matsumoto. Applicant respectfully requests withdrawal of this rejection.

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CONCLUSION


In light of the Applicant's amendments to the claims and the foregoing Remarks, it is respectfully submitted that the present application is in condition for allowance. The grounds for rejection which are not discussed here are moot. Should the Examiner have any remaining concerns which might prevent the prompt allowance of the application, the Examiner is respectfully invited to contact the undersigned at the telephone number appearing below.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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